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SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))	Attorney Docket No.	06132/065003
	Serial No.	10/789,842
	Applicant	Thomas P. Monath et al.
	Filing Date	February 27, 2004
	Group	1648
	IDS Filed	October 11, 2007

U.S. PATENT DOCUMENTS			
Examiner's Initials	Document Number	Publication Date/Filing Date	Patentee or Applicant
	6,136,561	Oct. 24, 2000	Ivy et al.
	6,416,763	Jul. 9, 2002	McDonell et al.
	6,682,883	Jan. 27, 2004	Monath and Nichols, Jr.
	6,878,372	Apr. 12, 2005	Monath and Arroyo
	2003/0044773	Mar. 6, 2003	Kleanthous et al.
	2004/0259224	Dec. 23, 2004	Guirakhoo
	2005/0053624	Mar. 10, 2005	Arroyo et al.
	2007/0184469	Aug. 9, 2007	Depres and Cateau
	08/807,445	Feb. 28, 1997	Chambers et al.
	09/007,664	Jan. 15, 1998	Chambers et al.

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION				
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Translation (Yes/No)
	WO 02/072835	Sept. 19, 2002	W.I.P.O.	
	WO 02/102828	Dec. 27, 2002	W.I.P.O.	
	WO 03/063725	Aug. 7, 2003	W.I.P.O.	
	WO 03/101397	Dec. 11, 2003	W.I.P.O.	
	WO 03/103571	Dec. 18, 2003	W.I.P.O.	
	WO 04/045529	Jun. 3, 2004	W.I.P.O.	
	WO 05/040390	May 6, 2005	W.I.P.O.	No
	WO 05/049815	June 2, 2005	W.I.P.O.	
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	WO 05/082020	Sept. 9, 2005	W.I.P.O.	
	WO 06/044857	Apr. 27, 2006	W.I.P.O.	
	WO 06/116182	Nov. 2, 2006	W.I.P.O.	
	WO 07/051267	May 10, 2007	W.I.P.O.	

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
	Allison et al., "Mapping of Functional Elements in the Stem-Anchor Region of Tick-Borne Encephalitis Virus Envelope Protein E," <i>J. Virology</i> 73:5605-5612, 1999.
	Allison et al., "Mutational Evidence for an Internal Fusion Peptide in Flavivirus Envelope Protein E," <i>J. Virology</i> 75:4268-4275, 2001.
	Arroyo et al., "ChimeriVax-West Nile Virus Live-Attenuated Vaccine: Preclinical Evaluation of Safety, Immunogenicity, and Efficacy," <i>J. Virology</i> 78:12497-12507, 2004.
	Bancroft, "Current Status of Dengue Vaccines and Prospects for the Future," <i>Puerto Rico Health Sci. J.</i> 6(1):23-26, 1987. Abstract only.
	Barrett, "Current Status of Flavivirus Vaccines," <i>Ann. N. Y. Acad. Sci.</i> 951:262-271, 2001.
	Bonaldo et al., "The Yellow Fever 17D Vaccine Virus as a Vector for the Expression of Foreign Proteins: Development of New Live Flavivirus Vaccines," <i>Mem. Inst. Oswaldo Cruz, Rio de Janeiro</i> 95(Suppl. 1):215-223, 2000.
	Bonaldo et al., "Surface Expression of an Immunodominant Malaria Protein B Cell Epitope by Yellow Fever Virus," <i>J. Mol. Biol.</i> 315:873-885, 2002.
	Bonaldo et al., "Attenuation of Recombinant Yellow Fever 17D Viruses Expressing Foreign Protein Epitopes at the Surface," <i>J. Virology</i> 79:8602-8613, 2005.
	Bonaldo et al., "Expression of Foreign Protein Epitopes at the Surface of Recombinant Yellow Fever 17D Viruses Based on Three-Dimensional Modeling of Its Envelope Protein," <i>Cell Biochem. Biophys.</i> 44:313-324, 2006.
	Cardosa, "Dengue Vaccine Design: Issues and Challenges," <i>British Med. Bull.</i> 54(2):395-405, 1998.
	Carle et al., "Experiments on the Transmission of an Icterogenic Agent in Yellow Fever Vaccine to Horses and Swine," <i>J. Bacteriol.</i> 48:45-69, 1944.

EXAMINER	DATE CONSIDERED
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(37 C.F.R. § 1.98(b))			

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
	Davis et al., "West Nile Virus Recombinant DNA Vaccine Protects Mouse and Horse from Virus Challenge and Expresses <i>In Vitro</i> a Noninfectious Recombinant Antigen That Can Be Used in Enzyme-Linked Immunosorbent Assays," <i>J. Virology</i> 75:4040-4047, 2001.
	Dermime et al., "Vaccine and Antibody-Directed T Cell Tumour Immunotherapy," <i>Biochim. Biophys. Acta</i> 1704:11-35, 2004.
	De Vries et al., "Genetic Manipulation of Equine Arteritis Virus Using Full-Length cDNA Clones: Separation of Overlapping Genes and Expression of a Foreign Epitope," <i>Virology</i> 270:84-97, 2000.
	Edelman et al., "Phase I Trial of 16 Formulations of a Tetravalent Live-Attenuated Dengue Vaccine," <i>Am. J. Trop. Med. Hyg.</i> 69(Suppl 6):48-60, 2003.
	EZ::TN TM Insertion System (Epicentre).
	Goryshin and Reznikoff, "Tn5 <i>In Vitro</i> Transposition," <i>J. Biol. Chem.</i> 273:7367-7374, 1998.
	Guirakhoo et al., "Immunogenicity, Genetic Stability, and Protective Efficacy of a Recombinant, Chimeric Yellow Fever-Japanese Encephalitis Virus (ChimeriVax-JE) as a Live, Attenuated Vaccine Candidate Against Japanese Encephalitis," <i>Virology</i> 257:363-372, 1999.
	Guirakhoo et al., "Recombinant Chimeric Yellow Fever-Dengue Type 2 Virus is Immunogenic and Protective in Nonhuman Primates," <i>J. Virology</i> 74:5477-5485, 2000.
	Guirakhoo et al., "Construction, Viremia, and Immunogenicity Profile of Recombinant Chimeric Yellow Fever/Dengue Viruses in Nonhuman Primates," Program and Abstracts of the 49 th Annual Meeting of the American Society of Tropical Medicine and Hygiene, Houston, Texas, October 29-November 2, 2000, Supplement to <i>Am. J. Trop. Med. Hyg.</i> , 313, Abstract.
	Guirakhoo et al., "Construction, Viremia, and Immunogenicity Profile of Recombinant Chimeric Yellow Fever/Dengue Viruses in Nonhuman Primates," Program and Abstracts of the 49 th Annual Meeting of the American Society of Tropical Medicine and Hygiene, Houston, Texas, October 29-November 2, 2000, Supplement to <i>Am. J. Trop. Med. Hyg.</i> , 1722, Abstract.
	Guirakhoo et al., "Development of ChimeriVax TM -Yellow Fever Based Vaccines for Dengue and Japanese Encephalitis Viruses," 6 th International Symposium on Positive Strand RNA Viruses, Paris, May 28-June 2, 2001, Abstract.
	Guirakhoo et al., "Viremia and Immunogenicity in Nonhuman Primates of a Tetravalent Yellow Fever-Dengue Chimeric Vaccine: Genetic Reconstructions, Dose Adjustment, and Antibody Responses Against Wild-Type Dengue Virus Isolates," <i>Virology</i> 298:146-159, 2002.
	Guirakhoo et al., "Safety and Efficacy of Chimeric Yellow Fever-Dengue Virus Tetravalent Vaccine Formulations in Nonhuman Primates," <i>J. Virology</i> 78(9):4761-4775, 2004.

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	Guirakhoo et al., "Live Attenuated Chimeric Yellow Fever Dengue Type 2 (ChimeriVax™-DEN2) Vaccine: Phase I Clinical Trial for Safety and Immunogenicity," <i>Human Vaccines</i> 2(2):60-67, 2006.
	Guy et al., "Evaluation by Flow Cytometry of Antibody-Dependent Enhancement (ADE) of Dengue Infection by Sera from Thai Children Immunized with a Live-Attenuated Tetravalent Dengue Vaccine," <i>Vaccine</i> 22:3563-3574, 2004.
	Halstead and Deen, "Rapid Review: The Future of Dengue Vaccines," <i>The Lancet</i> 360:1243-1245, 2002.
	Innis and Eckels, "Progress in Development of a Live-Attenuated, Tetravalent Dengue Virus Vaccine by the United States Army Medical Research and Materiel Command," <i>Am. J. Trop. Med. Hyg.</i> 69(Suppl 6):1-4, 2003.
	Johnson et al., "Growth Characteristics of Chimerivax™-Den2 Vaccine Virus in <i>Aedes Aegypti</i> and <i>Aedes Albopictus</i> Mosquitoes," <i>Am. J. Trop. Med. Hyg.</i> 67:260-265, 2002.
	Kolaskar and Kulkarni-Kale, "Prediction of Three-Dimensional Structure and Mapping of Conformational Epitopes of Envelope Glycoprotein of Japanese Encephalitis Virus," <i>Virology</i> 261:31-42, 1999.
	Kurane et al., "Immunity and Immunopathology in Dengue Virus Infections," <i>Sem. Immunol.</i> 4(2):121-127, 1992. Abstract only.
	Lai and Monath, "Chimeric Flaviviruses: Novel Vaccines Against Dengue Fever, Tick-Borne Encephalitis, and Japanese Encephalitis," <i>Adv. Virus Res.</i> 61:469-509, 2003.
	Laoprasopwattana et al., "Dengue Virus (DV) Enhancing Antibody Activity In Preillness Plasma does not Predict Subsequent Disease Severity or Viremia in Secondary DV Infection," <i>J. Infect. Dis.</i> 192:510-519, 2005. Erratum in <i>J. Infect. Dis.</i> 192:1863, 2005.
	Lee and Lobigs, "Mechanism of Virulence Attenuation of Glycosaminoglycan-Binding Variants of Japanese Encephalitis Virus and Murray Valley Encephalitis Virus," <i>J. Virology</i> , 76:4901-4911, 2002.
	Li et al., "Chimeric Influenza Virus Induces Neutralizing Antibodies and Cytotoxic T Cells Against Human Immunodeficiency Virus Type 1," <i>J. Virology</i> 67(11):6659-6666, 1993.
	Mandl et al., "Attenuation of Tick-Borne Encephalitis Virus by Structure-Based Site-Specific Mutagenesis of a Putative Flavivirus Receptor Binding Site," <i>J. Virology</i> , 74:9601-9609, 2000.
	Mandl et al., "Adaptation of Tick-Borne Encephalitis Virus to BHK-21 Cells Results in the Formation of Multiple Heparan Sulfate Binding Sites in the Envelope Protein and Attenuation <i>In Vivo</i> ," <i>J. Virology</i> 75:5627-5637, 2001.
	McAllister et al., "Recombinant Yellow Fever Viruses are Effective Therapeutic Vaccines for Treatment of Murine Experimental Solid Tumors and Pulmonary Metastases," <i>J. Virology</i> 74(19):9197-9205, 2000.
	Modis et al., "A Ligand-Binding Pocket in the Dengue Virus Envelope Glycoprotein," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 100(12):6986-6991, 2003.

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	Monath et al., "Recombinant, Chimaeric Live, Attenuated Vaccine (ChimerVax™) Incorporating the Envelope Genes of Japanese Encephalitis (SA14-14-2) Virus and the Capsid and Nonstructural Genes of Yellow Fever (17D) Virus is Safe, Immunogenic and Protective in Non-Human Primates," <i>Vaccine</i> 17:1869-1882, 1999.
	Monath et al., "Chimeric Yellow Fever Virus 17D-Japanese Encephalitis Virus Vaccine: Dose-Response Effectiveness and Extended Safety Testing in Rhesus Monkeys," <i>J. Virology</i> 74:1742-1751, 2000.
	Monath et al., "Yellow Fever 17D as a Vector for Vaccines Against Heterologous Flaviviruses," American Society for Virology, 19 th Annual Meeting, Colorado State University, Fort Collins, Colorado, July 8-12, 2000, Abstract W17-7, p. 85.
	Monath, "Prospects for Development of a Vaccine Against the West Nile Virus," <i>Ann. N.Y. Acad. Sci.</i> 951:1-12, 2001.
	Monath et al., "West Nile Virus Vaccine," <i>Curr. Drug Targets Infect. Disord.</i> 1:1-14, 2001.
	Monath, "Yellow Fever: an Update," <i>Lancet Infect. Dis.</i> 1:11-20, 2001.
	Monath et al., "Clinical Proof of Principle for ChimeriVax™: Recombinant Live, Attenuated Vaccines Against Flavivirus Infections," <i>Vaccine</i> 20:1004-1018, 2002.
	Morens and Halstead, "Measurement of Antibody-Dependent Infection Enhancement of Four Dengue Virus Serotypes by Monoclonal and Polyclonal Antibodies," <i>J. Gen. Virol.</i> 71(12):2909-2914, 1990.
	Pervikov, "Development of Dengue Vaccine," W.H.O. Dengue Bulletin 24, 2000.
	Poidinger et al., "Molecular Characterization of the Japanese Encephalitis Serocomplex of the Flavivirus Genus," <i>Virology</i> 218:417-421, 1996.
	Rey, "Dengue Virus Envelope Glycoprotein Structure: New Insight Into Its Interactions During Viral Entry," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 100(12):6899-6901, 2003.
	Rothman, "Dengue: Defining Protective Versus Pathologic Immunity," <i>J. Clin. Invest.</i> 113(7):946-951, 2004.
	Ryman et al., "Yellow Fever Virus Envelope Protein has Two Discrete Type-Specific Neutralizing Epitopes," <i>J. Gen. Virology</i> 78:1353-1356, 1997.
	Sabchareon et al., "Safety and Immunogenicity of Tetravalent Live-Attenuated Dengue Vaccines in Thai Adult Volunteers: Role of Serotype Concentration, Ratio, and Multiple Doses," <i>Am. J. Trop. Med. Hyg.</i> 66:264-272, 2002.
	Stephenson, "Flavivirus Vaccines," <i>Vaccine</i> 6(6):471-480, 1988. Abstract only.
	Sun et al., "Vaccination of Human Volunteers with Monovalent and Tetravalent Live-Attenuated Dengue Vaccine Candidates," <i>Am. J. Trop. Med. Hyg.</i> 69(Suppl 6):24-31, 2003.

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	Tesh et al., "Efficacy of Killed Virus Vaccine, Live Attenuated Chimeric Virus Vaccine, and Passive Immunization for Prevention of West Nile Virus Encephalitis in Hamster Model," <i>Emerg. Infect. Dis.</i> 8:1392-1397, 2002.
	Theiler and Smith, "The Use of Yellow Fever Virus Modified by <i>In Vitro</i> Cultivation for Human Immunization," <i>Rev. Med. Virol.</i> 10:3-16, 2000.
	Van Der Most et al., "Chimeric Yellow Fever/Dengue Virus as a Candidate Dengue Vaccine: Quantitation of the Dengue Virus-Specific CD8 T-Cell Response," <i>J. Virology</i> 74:8094-8101, 2000.
	Vlaycheva et al., "Yellow Fever 17D Virus: Pseudo-Revertant Suppression of Defective Virus Penetration and Spread by Mutations in Domains II and III of the E protein," <i>Virology</i> 327:41-49, 2004.
	Volk et al., "Solution Structure and Antibody Binding Studies of the Envelope Protein Domain III from the New York Strain of West Nile Virus," <i>J. Biol. Chem.</i> 279:38755-38761, 2004.
	Yamshchikov et al., "An Attenuated West Nile Prototype Virus is Highly Immunogenic and Protects Against the Deadly NY99 Strain: A Candidate for Live WN Vaccine Development," <i>Virology</i> , 330:304-312, 2004.
	Yang et al., "Induction of Potent Th1-Type Immune Responses from a Novel DNA Vaccine for West Nile Virus New York Isolate (WNV-NY1999)," <i>J. Infect. Dis.</i> 184:809-816, 2001.
	International Search Report from WO02/102828 dated April 18, 2003.
	International Search Report from WO03/063725 dated June 25, 2003.
	International Search Report from WO03/101397 dated September 4, 2003.
	International Search Report from WO03/103571 dated December 12, 2003.
	International Search Report from WO04/045529 dated June 28, 2004.
	International Search Report from WO05/082020 dated September 30, 2005.
	International Search Report from WO06/044857 dated May 30, 2006.
	International Search Report from WO06/116182 dated July 17, 2006.
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